REMARKS

Claims 1, 5, 6, 8, 11 and 15–29 are pending in the application. Claims 1 and 8 and 11 have been amended. Claim 18-20 have been added. Support for the amendments and new claims can be found in the specification as originally filed. No new matter has been added.

REJECTIONS UNDER 35 USC 103

Claims 1-3, 5, 6, 8, 10, 11 and 14–17 stand rejected under 35 USC 103(a) as being unpatentable over Runnells et al. (US 3,752,145) in view of Niehoff (US 5,662,612). This rejection should be withdrawn in view of the remarks and amendments made herein.

It is well settled that to establish a *prima facie* case of obviousness, the USPTO must satisfy all of the following requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification does not have a reasonable expectation of success, as determined from the vantage point of one of ordinary skill in the art at the time the invention was made. *Amgen v. Chugai Pharmaceutical Co.* 18 USPQ 2d 1016, 1023 (Fed Cir, 1991), *cert. denied* 502 U.S. 856 (1991). Third, the prior art reference or combination of references must teach or suggest all of the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496, (CCPA 1970).

The Office Action alleges that Runnells teaches a method of operating an injector, including that a "tube is then attached to the outlet 22 of the syringe and the free end of the tube is submerged in contrast solution. Air is bled from the syringe by advancing the piston plate 14 toward the outlet 22. Additional contrast solution may then be drawn through the tube into the syringe housing by retracting the piston plate." Further, the Office Action alleges that "Niehoff discloses a power injector which automatically senses the presence and capacity of a syringe and advances and retracts the plunger automatically (see Abstract)."

Applicants' invention of Claims 1, 8 and 11 has been amended to include subject

matter of "preprogramming or manually programming a predetermined fluid volume into the injector" and "retracting the piston based on the predetermined fluid volume to retract the plunger..." The novel aspects of Applicants' invention include that the piston primes not only the syringe but also the tube, without operator input, after the syringe is mounted.

Although the Office Action alleges that Runnells teaches "...Air is bled from the syringe by advancing the piston plate 14 toward the outlet 22," there is no teaching or suggestion of Applicants' invention. Rather, Runnells disclosure is limited to one in which:

> "[c]ontrast solution is poured into the syringe housing and the head 40 is replaced. A tube is then attached to the outlet 22 of the syringe and the free end of the tube is submerged in contrast solution. Air is bled from the syringe by advancing the piston plate 14 toward the outlet 22. Additional contrast solution may then be drawn through the tube into the syringe housing by retracting the piston plate. The contents of the safety chamber 46 may then be viewed through the transparent wall 42 of the magnifying safety head. If bubbles are noted, the piston plate is advanced and retracted once more to expel the entrapped air and to replace the desired volume of contrast solution. The contents of the safety chamber are again viewed, and the piston plate may again be advanced and retracted as often as necessary until no bubbles are observed through the magnifying walls 42 of the head 40.
>
> Sometimes it is convenient to eliminate the step of filling the syringe housing through the tip end, but in any event, the presence of entrapped air is determined by visual observation with the magnifying head up and the syringe as nearly vertical as possible, and after all observed air is expelled, injections should be given with the outlet down and the syringe as nearly vertical as the angiographic procedure permits. (col. 3, lines 4-28, *Emphasis Added*).

Thus, Runnells requires operator intervention in at least two ways after the syringe is loaded into the injector. Namely, intervention includes at least: (1) visual observation of whether entrapped air is present in the syringe and (2) manual advancement/retraction of the piston plate to remove air. Thus, Runnells requires that the operator provide input after the syringe is mounted into the injector, and therefore teaches away from Applicants' invention of Claims 1, 8 and 11.

The Office Action further alleges correctly that Runnells does not disclose sensing the syringe and automatically advancing the piston. The Office Action, however, alleges that Niehoff discloses automatically sensing presence and capacity of

a syringe and advances and retracts the plunger automatically. Further, the Office Action alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the automated power injector of Niehoff with loading and priming methods of Runnells. Rather, Niehoff does not remedy the deficiencies of Runnells.

Niehoff is directed to a computer-controlled injector that requires steps that are entirely different that Applicants' invention, namely, operator intervention, after the installation of the syringe, by either moving the plunger driver when the syringe is empty or no advancement of the plunger driver when the computer detects physical indicia on the syringe or extender (e.g. that the syringe is prefilled or preloaded). (Col. 3, line 48 – Col. 4, line 3).

In the first instance, if the syringe is an empty syringe, then Neihoff requires some input beyond just sensing that the syringe has been installed in the injector. The operator must manually begin movement of the plunger drive to position the plunger drive near the plunger (col. 5, lines 1-22). In the second instance, if the syringe is prefilled or preloaded, then there will be no advancement to the plunger because the plunger drive will be positioned at the rearward end of the syringe upon installation because in a prefilled syringe the plunger will be at the rearward end of the syringe or the extender will be at the rearward end of the syringe and in operative connection of the forward located plunger (See Fig. 1a and 1b), and therefore, no advancement will be required to get the plunger driver to engage with the plunger and any additional advancement would cause the fluid to expel from the syringe.

Accordingly, Niehoff only permits automatic movement to position the plunger in the syringe, but does not have the ability to move the syringe based on any predetermined fluid volume to prime both the syringe and the patient tube connected to a syringe. Neihoff only allows simple filling and expelling of fluid in and out of the syringe, and does not suggest any method to automate any fluid movement such that priming the syringe and the patient tube could be accomplished. Thus, Niehoff does not teach or suggest any "preprogramming or manually programming a predetermined fluid volume into the injector," "retracting the piston based on the predetermined fluid volume to retract the plunger" or "automatically advancing without operator input, the

piston to prime the syringe and a tube connected to the syringe."

Thus, neither Runnells nor Niehoff, alone or in combination, teach or suggest Applicants' invention of Claims 1, 8 or 11. Accordingly, Claims 1, 8 and 11 are believed to be patentable over Runnells in view of Niehoff. Reconsideration is requested.

Regarding Claims 16 and 17, Claims 16 and 17 are directed to "advancing the piston during the step of retracting the piston to retract the plunger and aspirate fluid..." However, neither Runnells nor Niehoff teach or suggest this novel feature of Applicants' invention. Therefore, reconsideration is requested.

Claims 5, 6 10 and 15-16 depend, either directly or indirectly, from Claim 1, 8 and 11, which as discussed herein is believed to be allowable. Thus, Claims 5, 6, 10 and 14-16 are also believed to be allowable. Accordingly, reconsideration of Claims 1, 5, 6, 8, 10, 11 and 14-17 is respectfully requested.

NEW CLAIMS

New Claims 18, 19 and 20 have been added and depends from Claims 1, 8 and 11, respectively. Neither Runnells not Niehoff, either alone or in combination teach this novel feature. Support for this can be found in the specification as originally filed including page 59, para 2, to page 60, para 2). Accordingly, Claims 18, 19 and 20 are believed to be in condition for allowance.

In view of the above amendments and remarks, Applicants submit that the claims are in condition for allowance and the Examiner would be justified in allowing them.

Respectfully submitted,

Dated: August 7, 2008

By /jill Denesvich/
Jill Denesvich
Attorney for Applicant(s)
Registration No. 52,810